AUG 2 0 2004

510(k) Summary

Submitter Name	Terang Nusa Sdn Bhd
Submitter Address	1 , Jalan 8 Pengkalan Chepa 2 Industrial Zone 16100 Kota Bharu, Kelantan , Malaysia.
Submitter Telephone	+60 9 7747171
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Contact Person	LOW , Chin Guan
Date of preparation	09 May 2004
Trade Name	NUZONE X2
Common Name	Sterile Neoprene - Polyisoprene Synthetic surgical glove, Powderfree, Polymer coated.
Classification	Surgeon's Glove
Legally marketed device to which substantial equivalence is being claimed.	The NUZONE X2, described in this 510(k) is substantially equivalent to the NUZONE Nitrile Surgical Gloves Powderfree that is currently marketed.
Description of device	NUZONE X2 ,powderfree surgical glove meets the requirements for surgical gloves described by the American Standard for Testing and Material ASTM D 3577 – 01a^{e2}.
Intended Use of the device	NUZONE X2 surgical gloves are disposable and sterile devices intended to be worn by healthcare personnel to prevent cross contamination between the user and the patient during procedures.

510 K Summary (continued)

Brief description of non-clinical tests	Test conducted per ASTM D 3577 – 01a$^{\varepsilon 2}$, ASTM D512 indicates that the product meet the requirements. Primary Skin Irritation test ASTM F 719-81 and Dermal Sensitization Test ASTM F 720-81 (86) indicates no sensitization or irritation.
Brief description of clinical tests	Not required
Conclusion drawn from clinical and non clinical tests	It can be concluded that NUZONE X2 Neoprene - Polyisoprene synthetic powderfree surgical glove will perform according to the performance standards referenced and therefore meets ASTM standards. FDA requirements and labeling claims. This device is substantially equivalent to the currently marketed devices.
Additional information deemed necessary by the FDA	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Chin-Guan Low
Director
Terang Nusa SDN BHD
1, Jalan 8, Pengkalan
Chepa 2 Industrial Zone,
16100 Kota Bharu,
MALAYSIA

Re: K041436
Trade/Device Name: Neoprene-Polyisoprene Synthetic Surgical Glove-Powderfree NUZONE X2
Regulation Number: 878.4460
Regulation Name: Surgeon's Glove
Regulatory Class: I
Product Code: KGO
Dated: August 6, 2004
Received: August 9, 2004

Dear Mr. Low:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3. Indication for use Statement

Submitter	:	Terang Nusa Sdn Bhd
510(k) Number	:	K041436
Device Name	:	Neoprene - Polyisoprene Synthetic Surgical Glove - Powderfree
Trade Name	:	NUZONE X2

Indication for use :

This surgical glove is a device made of a neoprene – polyisoprene synthetic material intended to be worn by operating room personnel to protect a surgical wound from contamination.

Prescription Use _____ *OR* Over the counter X
(Per 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDHR Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K041436